California Medical Device Recall Information

Recall Name
Medtronic Recalls SynchroMed II and SynchroMed EL Implantable Drug Infusion Pumps Due to Electrical Shorting

Recall Date	Product Description	Recalling Firm	Recall Reason
06/03/13	Implantable Infusion Pumps: • SynchroMed II • SynchroMed EL **External insulin pumps for diabetes are not affected.*	**Medtronic, Inc.** Minneapolis, MN	*There is potential for an electrical short circuit within the SynchroMed Infusion Pump.* *The short could present as a motor stall or an alarm/reset which could result in a loss of therapy, a return of underlying symptoms, or symptoms of withdrawal.*
Recall Class	**Product Identification**	**Distribution**	**Affected Dates**
I	SynchroMed II, **Model 8637** (20 ml or 40 ml reservoir sizes) SynchroMed EL Programmable Pump (10 ml or 18 ml reservoir sizes) **Models:** • **8626** • **8626L** • **8627** • **8627L**	**CA**, nationwide	Manufacture dates: May 1998 - June 2013 Distribution dates: April 1999 - June 2013

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm359111.htm